



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,462	01/22/2002	Michelangelo Scalone	20826	5548

151 7590 09/10/2003  
HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/054,462	<b>Applicant(s)</b> SCALONE ET AL.	
	<b>Examiner</b> Rebecca L Anderson	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                                                    |                                                                             |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 forms</u> . | 6) <input type="checkbox"/> Other:                                          |

### **DETAILED ACTION**

Claims 1-33 are currently pending in the instant application. Claims 1-31 are objected and claims 32 and 33 are withdrawn from consideration as being drawn to non-elected inventions.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 24 April 2002 and 03 September 2002 have been considered by the examiner.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-31 and the election of the compound of formula I wherein R1 and R2 are hydrogen and X is NH in the paper filed 30 June 2003 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the Examiner to search all of the claims at this time, that the process of Group I embraces the first step in the process of Group II and that applicant is not relying upon the patentability of the compound produced in order to achieve patentability of the claimed processes. These arguments are not found persuasive because :

- 1) The inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

2) Although the process of Group I may embrace the first step in the process of Group II, these processes are classified by the final product which they produce and as shown in the previous office action, the final products of these groups are classified in different subclasses of class 548 and 549. Therefore, the search of these independent processes would be separate from each other. Furthermore, the two processes are independent and distinct because they contain different reactants and/or reaction conditions and/or products and as such, restriction between the two is proper.

3) Even though applicant is not relying upon the patentability of the compound produced in order to achieve patentability of the claimed processes, it is still proper for the examiner to require a restriction between the groups I-III since groups I and II are independent and distinct processes which vary in reactants and/or reaction conditions and/or products, since groups II and III are processes which do not make the product of group III and the processes of groups II and III can be practiced with compounds other than the compound of group III and separate search considerations are involved.

The requirement is therefore, still deemed proper.

The election of the compound wherein R1 and R2 are hydrogen and X is NH has resulted in the following generic concept:

The process of preparing a compound of the formula (I) wherein:

R1, R2, Z, Ra, Rb and Rc, R3, R4, are as found in claim 1 and

X is N-Z.

The remaining subject matter of claims 1 and 3-31 that is not drawn to the above elected invention and the subject matter of claims 32 and 33 stands withdrawn under 37 CFR 1.142(b) as being for non elected subject matter. The remaining processes of claims 1 and 3-31 which are not within the generic concept, which are independent and distinct from the generic concept and do not have unity with the species elected and therefore are withdrawn by means of a restriction requirement within the claim are, for example, the processes for the preparation of the compounds of formula (I) wherein:

X is O or S.

The above mentioned withdrawn processes for the preparation of the compound of formula (I) (wherein X=O or S) which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition from the processes for the preparation of the compounds of formula (I) (wherein X= N-Z) of the elected invention. The withdrawn compounds contain varying functional groups which differ from those of the elected invention such as benzofuran (X=O) and benzothiophene (X=S) which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 548 subclass 469(+) (indole, X=N-Z), class 549 subclass 434(+) (benzofuran X=O) and class 549 subclass 32(+)(benzothiophene X=S). Therefore, again, the processes for the preparation of the compounds of the formula (I) which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but

the elected subject matter would not even render obvious the non-elected subject matter. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter.

These withdrawn processes for the preparation of the compounds of the formula (I) are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

### ***Objections***

Claims 1 and 3-31 are objected to as containing non-elected subject matter. Claims 1 and 3-31 presented drawn solely to the elected invention as identified supra would appear allowable over the prior art of record.

Claim 15 is objected to because of the following informalities: the number "13." appears within claim 15 and should be deleted. Appropriate correction is required.

Claim 2 is objected to as being dependent upon an objected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 2, which falls within applicants elected invention appears allowable over the prior art of record. The closest prior art of record is US Patent No. 6,291,685 which discloses the process for the preparation of hydroxybenzothiophene of formula I (column 17, line 35) comprising the cyclocarbonylation of a compound of formula II (column 17, line 45) to form the coarboxylic acid ester of the compound of formula I and thereafter saponifying said ester product to form the hydroxybenzothiophene of formula I (column 17, lines 30-67).


### Conclusion

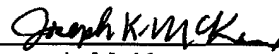
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.

  
\_\_\_\_\_  
Rebecca Anderson  
Patent Examiner  
Art Unit 1626, Group 1620

  
\_\_\_\_\_  
Joseph McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1620